DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

Clear Guide Medical
% Mr. Jack Kent
Director of Regulatory Affairs
40 Warrenton Road
BALTIMORE MD 21210

Re: K141806
Trade/Device Name: Clear Guide ONE
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: September 5, 2014
Received: September 8, 2014

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141806

Device Name
Clear Guide ONE

Indications for Use *(Describe)*

The Clear Guide ONE is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(per 21 CFR § 807.92)

Submitter's Information

Name	Clear Guide Medical
Address	40 Warrenton Road Baltimore, MD 20210
Phone Number	(410) 504-6540
Contact Person	Jack Kent, Director of Regulatory Affairs
Date Prepared	September 4, 2014

Device Information

Trade Name	Clear Guide ONE
Common Name	Tracking or Guidance System
Classification	Ultrasonic pulsed echo imaging system 21 CFR § 892.1560 (Product Code IYO)

Predicate Device Information

Device Name	AIM
510(k) Number	K121479

Device Description

The Clear Guide ONE is a medical device that tracks instrument positioning during ultrasound-guided procedures to provide instrument guidance to the end user. The device attaches directly to the transducer probe, and through optical detection technology, the Clear Guide ONE identifies and tracks any needle or needle-like rigid object entering the field of view. By coupling positioning information with the ultrasound image, the projected instrument pathway is displayed to the user for guiding instrumentation. The Clear Guide ONE is an accessory to an existing ultrasound machine and transducer probe.

Intended Use / Indications for Use

The Clear Guide ONE is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.

Technological Characteristics

As previously stated, the Clear Guide ONE operates using optical detection technology, instead of electromagnetic (EM) technology employed by the predicate device. Although both technologies can be used to track instrumentation and provide guidance, the optical detection technology does not require specialized instruments or calibration at the point of use. Performance data was collected to demonstrate that the Clear Guide ONE achieves its intended function in a manner that is as safe and as effective as the predicate device.

Similar to the predicate device, the Clear Guide ONE overlays instrument positioning data onto an existing ultrasound image through proprietary software algorithms.

Performance Data

Bench testing was performed to demonstrate that the Clear Guide ONE device could accurately achieve its intended use, showing that differences in technological characteristics from the predicate device did not affect device performance. Bench testing was performed by physicians to validate the device through end users. The results of bench testing show that the Clear Guide ONE is as safe and as effective as the predicate device. No clinical data was collected to support a substantial equivalence determination.

The Clear Guide ONE complies with the following recognized consensus standards:

IEC 60601-1-2 – Edition 3-2007 – Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility

IEC 60601-1 3rd Edition: Medical Electrical Equipment; Part 1 General Requirements for Safety

Conclusions

The Clear Guide ONE has the same intended use as the predicate device. Changes to the specific indications for use statement were made to account for technological differences, without impacting intended use. Differences in technology do not raise different questions of safety or effectiveness. Additionally, bench tests confirm that the Clear Guide ONE is as safe and as effective as the predicate device. Therefore, the Clear Guide ONE is substantially equivalent to its predicate device.